REMARKS

The Official Action dated February 25, 2005 has been carefully considered. Accordingly, the following remarks are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 23-28 are added. Support for these claims may be found in the specification and original claims. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 9-22 were rejected under 35 U.S.C. §102(b) as being anticipated by Duro et al, *FEBS Letters*, 399 (1996), 295-298. The Examiner asserted that Duro et al teach contacting serum with recombinant Par j 2 to detect pollen allergy and that the characterization of the recombinant antigen is a preliminary step for use of the protein therapeutically. The Examiner asserted that the preambles of the present claims add no additional limitations to the claims since the same product was used in the same method steps for identifying allergens for patients.

However, Applicants submit that the methods defined by claims 9-22 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 9, the invention is directed to a method for serologically identifying with improved accuracy the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes. The method comprises contacting serum with a pure allergen component of limited or no cross-reactivity. Thus, the present methods are for accurately identifying the actual sensitizing allergen among a variety of allergens. One skilled in the art will appreciate therefore that the present methods are not for generally diagnosing allergy, as the individual

has probably already been generally diagnosed with allergy. Rather, the present methods are for identifying to which particular allergen the individual is allergic, which can then be used by a physician in deciding a therapeutic strategy.

For example, in the specific embodiment involving *Parietaria* pollen, Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while pure rPar j 2 does not bind to IgE from such individuals. However, rPar j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen. Thus, Applicants have developed the present methods for specific identification of such an actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes by contacting serum with a pure allergen component of limited or no cross-reactivity. The ability to make such an accurate identification from a serum sample is obviously advantageous in allergy diagnosis and in allergy treatment.

Duro et al disclose the cloning and characterization of the allergen Par j 2.0101. While the authors mention that in a diagnostic/therapeutic approach, a preliminary step is to purify and characterize each major allergen, this is only a general statement relating to all allergens and all diagnostic and therapeutic strategies. Applicants find no teaching or suggestion regarding any specific diagnostic method or approach. Particularly, Applicants find no teaching or suggestion by Duro et al regarding a method for accurately identifying an actual sensitizing allergen among a variety of possible allergens as required by claim 9.

The Examiner asserted in the Official Action that the preambles of the present claims add no additional limitations to the claims since the same product was used in the same method steps for identifying allergens for patients. First, it is well settled that a preamble generally limits the claimed invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. *Catalina Mktg. Int'l, Inc. v.*

Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781 (Fed. Cir. 2002). Thus, if the preamble helps to determine the scope of the patent claim, then it is construed as part of the claimed invention; particularly, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816 (Fed. Cir. 1995). Additionally, when limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339, 66 USPQ2d 1271 (Fed. Cir. 2003). Thus, the Examiner may not disregard the preamble of claim 9.

When the preamble of claim 9 is properly recognized as part of the subject matter as a whole of the claimed invention, the distinctions between the claimed invention and the teachings of Duro et al become apparent. That is, Duro et al provide no teaching, suggestion or recognition of a method for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes. Moreover, contrary to the Examiner's assertion, Duro et al do not identify allergens for patients. Rather, the serum samples described at page 297 of Duro et al were from patients previously identified as allergic to *P. judaica* pollen or not allergic to Pj pollen.

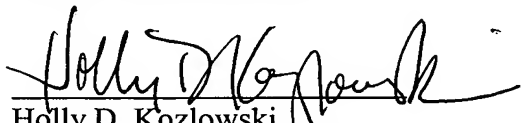
Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Duro et al to teach a method for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes, Duro et al do not anticipate the method of claim 9, or claims 10-22 dependent thereon.

In fact, dependent claim 10 further demonstrates the deficiencies in the teachings of Duro et al. Claim 10 recites the method according to claim 9 for selection of treatment of a disorder involving extract, proteins or peptides derived from said actual allergenic sensitizer. Not only do Duro et al fail to teach the method of claim 9, Applicants find no teaching by Duro et al regarding the use of such a method for selection of treatment involving extract, proteins or peptides derived from said actual allergenic sensitizer. One skilled in the art will recognize the significance of the present methods in the ability to select a safe and effective treatment of this type.

Accordingly, the methods defined by claims 9-22 are not anticipated by and are patentable over Duro et al, whereby the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. §102, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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